

**REMARKS**

Claims 1-36 are pending. Claims 19-22 and 31 are withdrawn from consideration. Claims 1-18, 23-30, and 32-36 stand rejected.

***Claim Objection is Traversed***

At page 2 of the Office Action, the Examiner asserted that the use of the abbreviation for "grams per liter" as "g/l" as provided in the claim 24 requires correction. While Applicants acknowledge that "g/L" is sometimes chosen, it is Applicants' position that the use of the lowercase "l" is well accepted by those of skill in the art and would not lead to any ambiguity or lack of clarity in present claim 24. Any number of U.S. patents have the lower case "l" used in this exact abbreviation in their claims, including, for example, U.S. Patent Nos. 6,521,452 and 6,492,174, which incidentally list Bruce Campell as primary examiner.

The lowercase "l" is the official abbreviation for "liter" and use of the upper case L should only be used if the lower case use is truly confusing. In this instance, it is not, as the person of ordinary skill would readily appreciate the abbreviation as standing for grams/liter.

Accordingly, it is believed that no amendment is necessary. Applicants respectfully request that the objection be withdrawn.

***Rejection of Claims under 35 U.S.C. §112, Second Paragraph is Traversed***

The Examiner rejected claims 1-18 and 32-26 as allegedly indefinite based on their recitation of the term "metal oxides." Based on the following remarks, Applicants respectfully traverse the rejection.

Fumed silica and other metal oxides disclosed and claimed in the present application are routinely (in fact, most commonly) referred to as "metal oxides" in the relevant art. Those of ordinary skill in the art would readily recognize the appropriate use of this term in Applicants' specification and claims. For example, Applicants note that Cabot Corporation, maker of CABOSIL (one example of fumed silica disclosed in the present application) use this term at <http://w1.cabot-corp.com/controller.jsp?N=23+4294967128+1000&entry=product> to characterize not only this fumed silica product, but also their fumed alumina. This widely

accepted nomenclature appears to be related to the common classification of silicon as "metalloid." The statement by the Examiner on page 3 of the Office Action that "the accepted term is 'non-metal oxides'" is simply incorrect.

Because the asserted basis for the rejection is in error, Applicants respectfully request that the rejection be withdrawn.

***Rejection of Claims under 35 U.S.C. §102(e) is Traversed***

The Examiner rejected claims 1-4, 7-8, 12-14, 29, 30, and 32-35 as allegedly anticipated by U.S. Patent No. 6,743,899 to Montalto (Montalto). The Examiner represented Applicants' claim 1 as:

1. method of preparing a solution containing biological material and adding metal oxide solution, wherein the pathogenic prion proteins are reduced in the resulting solution.

Office Action at page 3. Further, the Examiner stated that:

Montalto et al teaches all of the above limitations. Specifically, Montalto et al discloses the above method steps, including mixing SIPERNAT 50 or fumed silica with a biological material or more specifically, prion-infected lipoproteins (col. 14 and 15, under Example 2). Further, the biological material is blood-derived, specifically stemming from bovine serum (col. 14, Example 2).

Following the adsorption process, the lipoproteins are filtered out using 0.45 and 1 micron filters (col. 16, Example 2). This process reduces, eliminates and/or inactivated the transmissible spongiform encephalopathy agent as evaluated by assay by titration of Golden Syrian hamsters placed on test for 17 months (col. 17, Example 2).

Office Action at page 4. In view of the following remarks, Applicants respectfully traverse the rejection.

The Examiner has mischaracterized the recitation of Applicants' claim 1 and has failed to fully characterize the relevant aspects of the disclosure of Montalto. Applicants' pending claim 1 recites:

- A method of preparing a solution containing biological material,  
comprising  
    adding a metal oxide to biological material to obtain a solution comprising  
    a mixture of the metal oxide and the biological material; and  
    separating the metal oxide from the mixture to form a resulting solution,

wherein pathogenic prion proteins possibly contaminating the biological material are substantially reduced in the resulting solution.

It is clear from the language of pending claim 1 and the teaching of Applicants' specification that the metal oxide is separated from the mixture to form a "resulting solution" which is characterized by a substantial reduction in pathogenic prion proteins (which are associated with the metal oxide and are removed). See the Examples of Applicants' specification, showing that the metal oxides used are removed with at least some portion of contaminating prions, thereby providing a resulting solution having reduced amounts of pathogenic prion protein. As indicated, prion proteins are removed with the metal oxides, e.g., by filtration or centrifugation.

In contrast to the methods presently claimed, the material apparently taught as recovered (not discarded) in Montalto, allegedly with reduced prion protein, includes the lipoprotein with the SIPERNAT 50 (metal oxide). In Montalto, see, e.g., claim 24; and at col. 10, lines 1-16, the following passage:

In another embodiment, prions are removed from a lipoprotein material solution by contacting the solution with an adsorbant, preferably silica, *which binds more tightly to the lipoprotein than to the prion*. For example, the lipoprotein can be mixed with silica at a pH that does not cause the removal of the lipoprotein from the silica, typically between 6 and 8, and then the silica/lipoprotein particulate is separated from the prion-containing liquid by filtration. The lipoprotein is then removed from the silica using any appropriate method, for example, at an elevated pH. According to one embodiment, the recovery is carried out at a pH of about 10-11. According to another embodiment, the recovery is carried out by passing a high pH buffered solution through the lipoprotein-adsorbent complex until the lipoprotein is substantially removed from the adsorbent. After recovering the purified lipoproteins, the adsorbent can be discarded.

Emphasis added.

In Montalto, the adsorbant material (e.g., silica) is associated with the product to be recovered (lipoprotein), not the prion proteins. In contrast, Applicants teach and claim the use of metal oxides to remove prions from the desired material by binding prions and allowing them to be separated from the resulting solution containing the desired material. Accordingly, Montalto not only fails to disclose the Applicants' claimed invention, but teaches away from the claimed method by teaching that silica is not associated with prion but, rather, with a product to be recovered.

All of Applicants' pending claims 1, 2, 23, 29, 32, and 35 are similar to claim 1 as discussed above regarding the association of metal oxides with prion protein and removal of prions to form a resulting solution. For at least the foregoing reasons, Montalto could not possibly have anticipated Applicants' claimed invention.

***Rejection of Claims under 35 U.S.C. §103(a) is Traversed***

The Examiner rejected claims 9-11, 15-18, 23-28, and 36 as allegedly unpatentable over Montalto in view of U.S. Patent No. 6,221,614 to Prusiner, *et al.* (Prusiner). The Examiner stated that "Montalto et al do not teach modifying surface areas and weight ratios of silica for optimization or evaluating a sample for prion infectivity using an immunoassay . . ." Office Action at pages 5-6. The Examiner asserted that "Prusiner et al teach altering the weight ratio of silica to support material from 1:20 to 1:1 and modifying effective surface area to significantly remove prions from the biological fluid to undetectable levels." Office Action at page 6. In view of the foregoing and following remarks, Applicants respectfully traverse the rejection.

As noted above, Montalto does not disclose, teach, or suggest the removal of prions by the use of metal oxides (where, as presently claimed, the metal oxides are removed with the pathogenic prion protein). Prusiner fails to cure this deficiency and provides no teaching or suggestion of the use of metal oxides for removal of pathogenic prion proteins.

In the cited passage of Prusiner (col. 10, lines 32-45), Prusiner discusses the use of heteropoly acids for removal of prion proteins ( $\text{PrP}^{\text{Sc}}$ ). The Examiner appears to believe that the heteropoly acids discussed include metal oxides as presently claimed. This is not the case. The heteropoly acids are described as "complexing agents" and are discussed at length, with a number of citations provided, in columns 9 and 10 of Prusiner. However, there is no indication that this class of agent includes metal oxides as disclosed and claimed in the present application. In fact, the metal oxides of the present invention are not "heteropoly acids." At col. 9, lines 52-55, Prusiner states that "Heteropoly acids are fully or partially protonated forms of oxyanions having at least one central element and at least one coordinating element." One of ordinary skill in the art would readily recognize the heteropoly acids discussed by Prusiner do not include the metal oxides as presently claimed.

As a further example of a discussion illustrating the distinction between heteropoly acids and metal oxides according the present invention, the Examiner is referred to U.S. Patent No. 5,324,881, which discusses in Example 1 the use of fumed silica (CABOSIL) *as a support for* a heteropoly acid. This patent also illustrates the distinction throughout, including in the claim structure where materials such as amorphous silica and alumina are recited in claim 12 as support materials for the heteropoly acids recited in claim 1.

Prusiner fails to teach or suggest the use of metal oxide for removal of prion proteins as presently claimed, and Prusiner does not cure the noted deficiencies of Montalto. For at least this reason, the claimed invention could not be obvious in view of any combination of Montalto and Prusiner. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

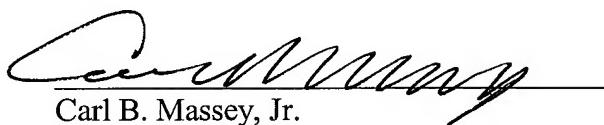
## CONCLUSIONS

It is believed that all asserted bases for rejection have been properly traversed. Accordingly, it is Applicants' position that the application is in condition for immediate allowance. Early notice to that effect is respectfully requested.

Should the Examiner have any questions regarding this reply, she is invited to contact Applicants' representative using the information provided below.

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